

Attorney Docket No. P63187US2  
Application No. 10/722,467

Remarks/Arguments:

The specification is amended to update the status of the parent application—now Pat. No. 6,696,429—and to add the §120 priority claim to the grandparent application—no. 09/192,184, filed Nov. 16, 1998, now Pat. No. 6,455,514. The cover page of (parent) Pat. No. 6,696,429, showing the §120 priority claim to the 09/192,184 (grandparent) application, is attached hereto.

Claims 12-20, presently amended, are pending.

Claims 1-11 are canceled, without prejudice or disclaimer.

Claim 12 is amended in order to more clearly define the instant invention. In accordance with the instant amendment, line 3 of claim 12 is amended by deleting the second occurrence of "to a human or"; thereby, clarifying that treatment of a human or animal "suffering from arthritis or from fractures" is excluded from the present claims. Claims 13-20 are amended, hereby, as explained below.

Claims 13-20 were rejected under 35 USC 112, 2<sup>nd</sup> ¶, for being indefinite, i.e., for being dependent on non-existing "claim 28." Reconsideration is requested.

First of all, Applicants wish to thank the Examiner for examining the rejected claims as if dependent on claim 12, notwithstanding the incorrectly recited dependencies. Secondly, each of the rejected claims is amended, hereby, to be dependent on "claim 12." Accordingly, withdrawal of the rejection appears to be in order.

Claim 12 was rejected under 35 USC 112, 2<sup>nd</sup> ¶, for allegedly being indefinite. Reconsideration is requested.

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The claim language at issue in the §112, ¶2, rejection, is "treating lameness that appears during osteoarthrosis comprising administration . . . to a human or to an animal not suffering from arthritis." According to the statement of rejection, "arthritis" is synonymous with "osteoarthrosis"—because "osteoarthrosis" is synonymous with "osteoarthritis" and because "osteoarthritis" is allegedly synonymous with "arthritis"—and, therefore, a patient suffering from "osteoarthrosis . . . by definition must be suffering from arthritis" (Office Action, page 2). Therefore, besides requiring that the language issue be corrected, the PTO interpreted and examined claim 12 without considering the limitation "not suffering from arthritis."

Applicants submit that the language at issue is not indefinite, allegations to the contrary by the PTO notwithstanding. Furthermore, the PTO erred by refusing to consider "not suffering from arthritis" a limitation on the claims, even if the language at issue were indefinite as alleged by the PTO.

The PTO must examine the claims taking into consideration all claim limitations. A limitation cannot be disregarded even if indefinite under §112, ¶2. As set forth in MPEP 2143.03 ("All Claim Limitations Must Be Taught or Suggested"):

. . . "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). . . .

**INDEFINITE LIMITATIONS MUST BE CONSIDERED**

A claim limitation which is considered indefinite cannot be disregarded. . . . *Ex parte Ionescu*, 222 USPQ 537 (Bd. Pat. App. & Inter. 1984) (Claims on appeal were rejected on indefiniteness grounds only; the rejection was reversed and the case remanded to the examiner for consideration of pertinent prior art.).

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Accordingly, it was improper for the PTO to disregard the limitation "not suffering from arthritis" in examining the claims, *Wilson, supra. Ionescu, supra*, MPEP 2143.03—especially, since the limitation patentably distinguishes the prior art as explained below. In any event, the language at issue is, in fact, not indefinite under §112, ¶2.

Merely that it requires some thought to understand the meaning of a claim term does not render the term indefinite under §112, ¶2. *S3 Inc. v. nVIDIA Corp.*, 59 USPQ2d 1745 (Fed. Cir. 2001).

The purpose of the claims is not to explain the technology or how it works, but to state the legal boundaries of the patent grant. A claim is not "indefinite" simply because it is hard to understand when viewed without benefit of the specification.

59 USPQ2d at 1748. It is applicants sole prerogative to define the claims. *In re Pilkington*, 162 USPQ 145, 148 (CCPA 1969). The claim terms used by applicants need not be "conventional" in the art, since a patent applicant is entitled to be his own lexicographer. *In re Castaing*, 166 USPQ 550 (CCPA 1970). The Examiner's definition of a claim limitation cannot conflict with the definition given in the specification, which must be used in construing the claims for purposes of examination. *In re Zletz*, 13 USPQ2d 1320 (Fed. Cir. 1989)

When the applicant states the meaning that the claim terms are intended to have, the claims are examined with that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art.

*Zletz*, 13 USPQ2d at 1322. Moreover, perhaps more importantly, the definition of a claim limitation given by the examiner cannot be different than would be given by one of ordinary skill in the art. *In re Cortright*, 49 USPQ2d 1464 (Fed. Cir. 1999).

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The statement of rejection correctly observes that osteoarthrosis is synonymous with osteoarthritis (therefore, hereafter it is referred to as "osteoarthrosis/osteoarthritis"). Osteoarthrosis/osteoarthritis is a chronic, *noninflammatory* bone-joint disorder, characterized by degeneration of cartilage found on the articular surfaces of bones. The resulting damage to the cartilage often causes hypertrophy of the bone under the cartilage and, additionally, modification of the synovial membrane.

"Arthritis," in contrast to *noninflammatory* osteoarthrosis/osteoarthritis, is an *inflammatory* bone-joint disorder. Moreover, the etiology and symptoms of osteoarthrosis/osteoarthritis differ from the etiology and symptoms of arthritis.

Lameness, as disclosed in the subject application (e.g., page 2, lines 7-27), is limb pain that is symptomatic of joint disorders resulting from mechanical stress, such as osteoarthrosis/osteoarthritis. As such, lameness can appear without being associated with any inflammatory disorder, such as arthritis. Accordingly, the presently claimed subject matter is specifically directed to lameness caused by osteoarthrosis/osteoarthritis in a patient "not suffering from arthritis."

The aforesaid distinctions between osteoarthrosis/osteoarthritis and arthritis—employed in accordance with the presently claimed intention—are well documented in the literature, e.g., as shown in the attached definitions from the references *On Line Medical Dictionary* (defining arthritis as "an inflammatory condition that affects joints," defining osteoarthritis as a "noninflammatory degenerative joint disease," and defining osteoarthrosis as "synonym: osteoarthritis"), *Grand*

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*Dictionnaire Terminologique* (listing as synonyms "osteoarthritis . . . osteo-arthritis . . . [and] noninflammatory arthritis"), and *Steadman's Online Medical Dictionary* (defining arthritis as "inflammation of a joint or a state characterized by inflammation of joints").

In view of the well known distinctions between osteoarthrosis/osteoarthritis and arthritis, as evidenced by the aforesaid (attached) definitions appearing in the literature, one of ordinary skill in the art would not have defined "arthritis" as a synonym for "osteoarthrosis/osteoarthritis." In that one of ordinary skill in the art would not have defined "arthritis" as a synonym for "osteoarthrosis/osteoarthritis," the examiner cannot use a different definition, i.e., one that renders "osteoarthrosis/osteoarthritis" synonymous with "arthritis." *Cortright, supra*. Even if some thought is required to appreciate the distinction between "osteoarthrosis/osteoarthritis" and "arthritis," this fails to render claim 12 indefinite under § 112, ¶2. *S3 Inc., supra*.

Claims 12, 15, 17, 18, and 20 were rejected under 35 U.S.C. 102(b) as being allegedly anticipated by U.S. 4876248 (Brelriere) and, additionally, by applicant's alleged admission. Reconsideration is requested.

For anticipation under § 102 to exist, each and every claim limitation, as arranged in the claim, must be found in a single prior art reference. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 USPQ 253 (Fed. Cir. 1985). The absence from a prior art reference of a single claim limitation negates anticipation. *Kolster Speedsteel A B v. Crucible Inc.*, 230 USPQ 81 (Fed. Cir. 1986). A reference that discloses "substantially the same invention" is not an anticipation. *Jamesbury Corp.* To anticipate the claim, each claim limitation must "identically appear" in the

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reference disclosure. *Gechter v. Davidson*, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997) (*emphasis added*). To be novelty defeating, a reference must put the public in possession of the identical invention claimed. *In re Donahue*, 226 USPQ 619 (Fed. Cir. 1985).

According to the statement of rejection, Breliere fully meets each of the rejected claims, i.e., as interpreted without taking in to account the limitation "not suffering from arthritis." As explained above, the aforesaid limitation—whether indefinite or not—must be considered when comparing the claims against the prior art. MPEP 2143.03. Since the PTO has failed to show that each limitation on the rejected claims—including the limitation "not suffering from arthritis"—is found in Breliere, the rejection under § 102(b) cannot be maintained. *Jamesbury, supra*.

In fact, moreover, the limitation "not suffering from arthritis," as recited in the rejected claims, is not found in the cited reference. Breliere discloses bisphosphonic acid derivatives having *anti-inflammatory* properties. As shown in the working examples of the reference, inhibiting the anti-inflammatory activity of the aforesaid derivatives on chondrocytes, *in vitro*, and inhibiting the anti-inflammatory activity of the aforesaid derivatives in an *arthritis* rat model (which rat model is widely used to evaluate the anti-inflammatory properties of potential medicaments, particularly for evaluating possible medicaments for treating rheumatoid arthritis (also known as inflammatory rheumatism), are effected by injection of *Mycobacterium tuberculosis*.

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Breliere does not even mention arthrosis, let alone osteoarthritis. As set forth, e.g., in the reference Abstract, Breliere is concerned with the "anti-inflammatory effect" of methylene-diphosphonic-acid derivatives.

While acknowledging that Breliere does not disclose treating lameness, the statement of rejection alleges (Office Action, page 5) "lameness is *inherently* treated by the compounds of Breliere" (*emphasis added*). The statement of rejection mistakenly relies on "inherently" obtained effects.

"In relying on a theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (*emphasis in original*). An argument by the PTO is "not prior art." *In re Rijckaert*, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

Non-disclosed *inherent* properties of a compound must not be confused with *unknown* properties of the compound. *In re Newell*, 13 USPQ 2d 1248, 1250 (Fed. Cir. 1989). When an effect of using a prior art compound, as taught in the prior art, would not have been appreciated by one skilled in the art, the effect amounts to "an unrecognized accident," which "cannot constitute an anticipation," because nothing in the prior art inherently suggests such an effect. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978).

In the present case, nothing in the record suggests that one skilled in the art would have realized that the treatment disclosed in Breliere inherently treated lameness, as well. Therefore, the

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statement of rejection mistakenly alleges (Office Action page 4) "the treatment of conditions due to inflammatory phenomena and in particular for the treatment of arthritic conditions" as taught in Breliere, anticipate the "process for treating lameness that appears during osteoarthritis," since any benefit in treating (noninflammatory) lameness would have been "an unrecognized accident," which "cannot constitute an anticipation," because nothing in Breliere inherently suggests such a benefit. *Marshall*, 198 USPQ at 346.

This of course assumes that lameness would have been, in fact, treated by following the teachings of Breliere, which is not the case. Breliere discloses the treatment only of patients suffering from an inflammatory joint disorder, such as arthritis. The statement of rejection, therefore, only speculates when alleging that these patients also suffered from lameness, and a rejection cannot be based on speculation. *In re Warner*, 154 USPQ 173 (CCPA 1967).

Since "treating lameness that appears during osteoarthritis" is neither taught nor suggested in Breliere and, further, since such treatment of a patient (human or animal) "not suffering from arthritis or from fractures" are limitations on the present claims that are absent from Breliere, anticipation based on Breliere is negated. *Kolster Speedsteel AB, supra*. Withdrawal of the rejection under §102(b) based on Breliere appears to be in order.

Withdrawal of the §102(b) rejection based on alleged admissions by applicants is indicated, at least, since it is based on the mistaken understanding that "arthritis" is synonymous with "osteoarthritis/osteoarthritis."



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Claims 13, 14, 16, and 19 were rejected under 35 U.S.C. 103(a) as being allegedly unpatentable based on Breliere in view of US5488041 (Barbier). Reconsideration is requested.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art," *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970), "and it is error to ignore specific limitations distinguishing over the [prior art] reference." *Ex parte Murphy*, 217 USPQ 479, 481 (PO Bd. App. 1982). A "ground of rejection is simply inadequate on its face . . . [when] the cited references do not support each limitation of [the] claim." *In re Thrift*, 63 USPQ2d 2002, 2008 (Fed. Cir. 2002).

The "evidence upon which the examiner relies must clearly indicate that a worker of routine skill in this art would view the claimed invention as being obvious." *Ex parte Wolters*, 214 USPQ 735, 736 (BPA&I 1982). "It is facts which must support the legal conclusion of obviousness." *Ex parte Crissy*, 201 USPQ 689, 695 (POBdApp 1976).

The Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because *it may doubt* that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis.

*Warner*, 154 USPQ at 178 (*emphasis in original*). When the

USPTO asserts that there is an explicit or implicit teaching or suggestion in the prior art, it must indicate where such a teaching or suggestion appears *in the reference*. . . . The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient to establish inherency. . . . [S]uch a retrospective view of inherency

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is not a substitute for some teaching or suggestion supporting an obviousness rejection.

*Rijckaert*, 28 USPQ2d at 1957 (*emphasis added*).

In the context of a rejection for obviousness under §103, the "Examiner bears [both] the initial burden . . . of presenting a *prima facie* case of unpatentability" and "the ultimate burden of persuasion on the issue." *In re Oetiker*, 24 USPQ 1443, 1444 and 1447 (Fed. Cir. 1992) (*emphasis, added*). "The Examiner can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art *would lead* that individual to combine the relevant references. . . . Indeed, the teachings of the references can be combined only if there is some suggestion or incentive to do so." *Ex parte Obukowicz*, 27 USPQ 1063, 1065 (BPA&I 1992)(*emphasis, added*).

In order to establish a *prima facie* case of obviousness, it is necessary for the examiner to present *evidence*,<sup>[1]</sup> preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, that one having ordinary skill in the art *would have been led* to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention [*citations, omitted*].

*Ex parte Levengood*, 28 USPQ2d 1300, 1300-01 (BPA&I 1993) (*emphasis in original*).

The fact that all elements of a claimed invention are known does not, by itself, make the combination obvious. *Ex parte Clapp*, 227 USPQ 972 (BPA&I 1985). To support a rejection for obviousness based on the combination of separate prior art teachings, the USPTO "must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination." *In re Rouffet*, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998). When the claimed invention requires modification of the prior art, there is no obviousness under §103 when "[t]he prior art does not

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suggest . . . [the] modification . . . or provide any reason or motivation to make the modification." *In re Laskowski*, 10 USPQ2d 1397, 1398 (Fed. Cir. 1989).

As explained above, Breliere discloses anti-inflammatory properties, only, of bisphosphonic acid and its use only in treating inflammatory conditions, such as arthritis. Breliere fails to meet the limitations "treating lameness that appears during osteoarthritis" and treatment of a patient (human or animal) "not suffering from arthritis or from fractures."

Barbier discloses a method for promoting bone repair following fracture or bone surgery. The reference neither teaches nor suggests—expressly or inherently—any beneficial activity on osteoarthritis/osteoarthritis-induced lameness. The person of ordinary skill in the art seeking to treat a *noninflammatory* condition or disorder, such as osteoarthritis/osteoarthritis, would not have been motivated by Barbier to use bisphosphonic acid derivatives.

Accordingly, nothing in the secondary reference Barbier cures these fatal deficiencies of Breliere in meeting each limitation on the present claims. Since each limitation on the rejected claims is not supported by the cited references, the rejection under §103(a) is "inadequate on its face." *Thrift*, 63 USPQ2d at 2008. Withdrawal of the rejection under §103(a), therefore, appears to be in order.

*Request for Acknowledgment of  
Foreign Priority Under 35 USC 119*

A claim to foreign priority under 35 USC 119(a) has been made (inventorship declaration of record) and the certified copy of the priority document—FR 98 12 388, filed October 2, 1998—filed was filed July 7, 1999, in grandparent application no. 09/192,184. Moreover, the

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foreign priority claim was awarded in the parent application, as shown on the aforesaid (attached) cover page of (parent) Pat. No. 6,696,429.

Accordingly, request is made that the Examiner mark the next Office Action to acknowledge, both, the claim to §119 foreign priority and receipt of the certified copy.

*Request for Examiner's Initialed Form PTO 1449*

On November 28, 2003, copies of Information Disclosure Statements, including completed Forms PTO 1449, and Form PTO 892 of record in the parent application were filed—together with the subject application—in the PTO. The references cited on the Forms PTO 1449 and Form PTO 892 were officially considered in the parent application, the as shown on the aforesaid (attached) cover page of (parent) Pat. No. 6,696,429.

Accordingly, it is requested that the PTO return the submitted Forms PTO 1449, initialed by the Examiner to show that the references cited, thereon, were considered by the Examiner during prosecution of the subject application.

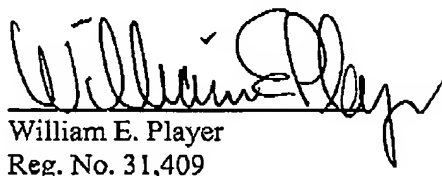
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Favorable action is requested.

Respectfully submitted,

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## arthritis

<rheumatology> An inflammatory condition that affects joints. Can be infective, autoimmune, traumatic in origin.

**Origin:** Gr. Arthron = joint

(18 Nov 1997)

**Previous:** arthritic calculus, arthritic general pseudoparalysis, arthritide, arthritides

Next: arthritis, adjuvant, arthritis deformans, arthritis degenerative

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## osteoarthritis

<pathology> Noninflammatory degenerative joint disease occurring chiefly in older persons, characterised by degeneration of the articular cartilage, hypertrophy of bone at the margins and changes in the synovial membrane. It is accompanied by pain and stiffness, particularly after prolonged activity.

Origin: Gr. Arthron = joint

(18 Nov 1997)

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Previous: ostentatious, ostentator, ostentive, ostentous, osteo-, osteoanagenesis

Next: osteoarthritis, hip, osteoarthropathy

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## osteoarthrosis

Synonym: osteoarthritis.

Origin: osteo-+ G. Arthron, joint, + -osis, condition

(05 Mar 2000)

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**Previous:** [osteopathopathy](#), [primary hypertrophic](#), [osteopathopathy](#), [secondary hypertrophic](#)

**Next:** [osteoblast](#), [osteoblastic](#), [osteoblastoma](#), [osteoblasts](#), [osteocalcin](#)

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1 / 1

Domaine(s) : - médecine  
symptomatology and pathology

anglais

français

arthrosis

arthrose n. f.

Sous-entrée(s) :

synonyme(s)

osteoarthritis

osteo-arthritis

degenerative joint disease

DJD

osteo-arthrosis

degenerative arthritis

noninflammatory arthritis

hypertrophic arthritis

senescent arthritis

[Office de la langue française, 2001]

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Grand dictionnaire terminologique

<http://www.stedmans.com/section.cfm/45>

## Online Medical Dictionary

arthrosis (ar-thrō'sis)

1. Syn: joint [G. *arthrōsis*, a jointing]
2. Syn: osteoarthritis [arthro- + G. *-osis*, condition]

Prev